

ORAJEL ANTISEPTIC ALCOHOL-FREE MOUTH SORE RINSE- hydrogen peroxide, menthol liquid
Church & Dwight Co., Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Orajel Antiseptic Alcohol-Free Mouth Sore Rinse

Active ingredients

Hydrogen peroxide 1.5%

Menthol 0.1%

Purpose

Oral debriding agent/Oral antiseptic, Oral pain reliever

Uses

- first aid to help reduce bacteria in minor oral wounds
- for temporary pain relief and
- use in cleansing minor wounds or minor gum inflammation resulting from:
 - minor dental procedures
 - orthodontic appliances
 - dentures
 - accidental injury
 - canker sores
 - other irritations of the mouth and gums

Aids in the removal of:

- phlegm
- mucus
- other secretions associated with occasional sore mouth

Warnings

Do not use this product for more than 7 days unless directed by a dentist or healthcare provider

When using this product

- do not swallow
- do not exceed recommended dosage

Stop Use

Stop Use and see your physician promptly if

- swelling, rash or fever develops
- irritations, pain or redness persists or worsens
- sore mouth symptoms do not improve in 7 days

Keep out of reach of children

If more than used for rinsing is accidentally swallowed, get medical help or contact a poison Control Center right away

Directions

Adults and children 2 years of age and older

- Swish one-half capful (2 teaspoons=10mL) around the mouth over the affected area for at least 1 minute and then spit out. Use up to 4 times daily after meals and at bedtime or as directed by a dentist or healthcare provider

Children under 12 years of age

- Should be supervised in the use of this product

Children under 2 years of age

- Consult a dentist or healthcare provider

Other information

- cap tightly
- keep away from heat or direct sunlight
- do not use if safety seal is broken or missing

Inactive ingredients

blue 1, disodium EDTA, methyl salicylate, phosphoric acid, poloxamer 338, polysorbate 20, propylene glycol, sodium saccharin, sorbitol, water

Questions or comments?

Questions or comments call us at 1-800-952-5080 M-F 9am-5pm ET or visit our website at www.oraljel.com

Principal Display Panel

#1 ORAL PAIN RELIEVER BRAND FOR ADULTS

With PAIN RELIEF!

Orajel

ALCOHOL FREE

FOR ALL MOUTH SORES

ANTISEPTIC RINSE

Canker Sores Cheek Bites Gum Irritation Irritation from Dentures or Braces

Promotes Healing

Kills Bacteria

Provides Pain Relief

SOOTHING MINT RINSE

16 FL OZ (473.2 mL)

ORAL DEBRIDING AGENT/ANTISEPTIC RINSE/PAIN RELIEVER





ORAJEL ANTISEPTIC ALCOHOL-FREE MOUTH SORE RINSE

hydrogen peroxide, menthol liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10237-784 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 1 mg in 1 mL |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V) | HYDROGEN PEROXIDE | 15 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SORBITOL (UNII: 506T60A25R) | |
| WATER (UNII: 059QF0KO0R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) | |
| PHOSPHORIC ACID (UNII: E4GA8884NN) | |
| POLOXAMER 338 (UNII: F75JV2T505) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------|---|----------------------|--------------------|
| 1 | NDC:10237- | 473.2 mL in 1 BOTTLE; Type 0: Not a Combination | 11/01/2010 | |

| | | | |
|------------------------------|---|-----------------------------|---------------------------|
| 784-16 | Product | 11/01/2019 | |
| | | | |
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part356 | 11/01/2019 | |

Labeler - Church & Dwight Co., Inc. (001211952)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------|----------------|---------------|----------------------------|
| Church & Dwight Canada Corp. | | 253933600 | manufacture(10237-784) |

Revised: 9/2021

Church & Dwight Co., Inc.